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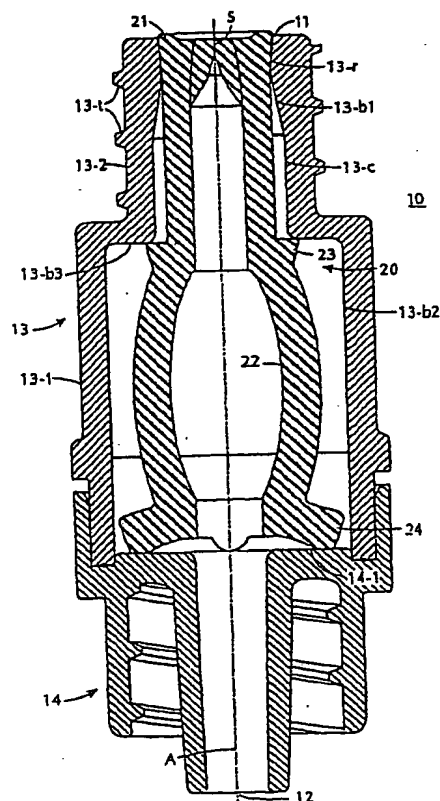
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(54) Title: **CONTROL OF FLUID FLOW**

(57) Abstract

A flow control device (10) with an inlet (11) for fluid and a slotted movable member (20) with a head portion (21) sealing the inlet and closing the slot (S). The unsealing of the inlet and the opening of the slot permits the passage of fluid therethrough. The movable member extends by a channel, which can be open or closed, between the inlet and an outlet and has a portion (22) which is expandable laterally. A member external to the flow control device, such as the tip of a Luer taper, can activate the movable member by depressing it to open the slot and allow the flow of fluid.



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## CONTROL OF FLUID FLOW

BACKGROUND OF THE INVENTION

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The invention relates to flow control and more particularly, to the control of fluid flow with respect to the infusion and aspiration of fluids in venous and arterial systems.

10

A common container for medical fluids is a plastic pouch which contains saline, or other solutions for patient infusion. The contents of such a container are carried by a conduit, typically plastic tubing, through a "check" valve that is used to prevent backflow.

15

In addition, other check valves can be used with the conduit to provide for the infusion and/or aspiration of other substances, such as medicaments, body fluids, and anesthetics. Infusion is commonly used to introduce saline or other medical fluids into veins, while aspiration is commonly used to draw fluids from body cavities.

20

~~The ordinary check valve used with conduits from medicinal containers functions by the deflection of an elastomeric element towards and away from a valve seat. The deflection is towards the valve seat in order to prevent flow, and away from the seat to permit flow.~~

25

In some cases the control of fluid is with respect to a multiplicity of channels that have varying degrees of convergence with one another. A typical multichannel arrangement makes use of connectors which permit the intercoupling of flow channels. For example, when two channels are to be joined to permit a common output, the connector can take the form of a fitting that resembles a "Y". When one of the channels terminates in an infusion site, the prior practice has been to access the site by needles, which are undesirable.

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Because of the desirability of achieving needleless injection and infusion of fluids, one effort has resulted in Rogers et al. U.S. Patent No. 5,006,114, in which a valve assembly has a Luer lock on an inlet, and movable piston seals the inlet.

1           When a syringe is attached to the Rogers inlet the  
piston is displaced to unseal a fluid channel which connects  
the end of the syringe to an outlet, and then to a device  
connected to a patient. When the syringe is removed from  
5   the inlet the piston is moved to its original closed  
position by an internal spring of the valve. The device  
suffers from the disadvantage that the requirement of a  
spring for acting against the piston results in a force  
against the inserted Luer tip that increases as the piston  
10   is displaced.

          In addition, the Rogers medical valve assembly  
provides an outlet channel that is displaced at an angle in  
relation to the inlet. As a consequence of this angular  
displacement, it is difficult to manufacture the device  
15   since there is a tendency for flash to accumulate at the  
entrance of the outlet channel in the vicinity of the  
piston. In addition, the angular configuration of the  
Rogers valve does not lend itself to manifold application.

          Moreover, the Rogers design is intended for a Luer  
20   fitting which does not have a taper so that when the  
conventional tapered Luer fitting is employed, it can become  
jammed in the straight line walls of the inlet.

          An attempt to overcome the disadvantages of Rogers  
is disclosed in Raines, U.S. Patent No. 5,147,333. In the  
25   Raines patent there is accommodation for a tapered Luer  
fitting, but there is the continued disadvantage of the  
necessity for using a spring to urge a piston or spool  
forwardly during closure of the valve and rearwardly when  
the valve is being opened. As a result, the disadvantageous  
30   increase in spring force with displacement continues to be  
present.

          Furthermore, the Raines "backcheck" valve requires a  
pair of vertically offset ports that extend laterally from a  
tubular body and the spool or piston is disposed between the  
35   ports. In addition, like the predecessor Rogers valve the  
piston or spool in Raines requires at least one projection  
from the end of the piston contacted by a Luer tip in order  
to permit the flow of fluid from the Luer tip through the  
valve.

1           In addition, like Rogers, the Raines valve is also  
subject to difficulties in manufacture because of flash  
since the various outlet ports are angularly, i.e.,  
perpendicularly, oriented in relation to their inlets.

5           Other arrangements are disclosed in Newgard, U.S.  
Patent No. 5,064,416; Sivert, U.S. Patent No. 4,915,687 and  
Jackson, U.S. Patent No. 4,429,856. These arrangements are  
complex, are difficult to manufacture and have numerous  
other disadvantages.

10           Another objection to existing arrangements is that  
their activators are not interchangeable. Thus injection  
sites that require needle injection cannot be used without  
needles; conversely injection sites that are externally  
actuated by inserting a member that opens a diaphragm cannot  
15   be used with needles. In addition, the non-needle injection  
sites present problems of sterility. In order to have  
external access to the control diaphragm, it is necessary to  
have an open channel that can become contaminated. Even  
when a temporary seal is provided for the open channel,  
20   removal of the seal prior to injection allows inadvertent  
contamination. This is by contrast with an injection site  
having a needle-puncturable surface. The latter can be  
wiped clean with a sterilizing agent before injection is to  
take place.

25           Accordingly, it is an object of the invention to  
achieve needleless injection, infusion and aspiration  
without the need for spring-loaded members, such as pistons  
or spools where the counterforce exerted by the spring  
increases as the piston is displaced. A related object of  
30   the invention is to overcome the disadvantages  
characterizing the needleless injection valves of Rogers,  
U.S. Patent No. 5,006,114 and Raines, U.S. Patent No.  
5,147,333.

35           A further object of the invention is to overcome the  
need for angular orientation of an outlet in relation to an  
inlet in order to avoid manufacturing difficulties such as  
the creation of flash which can clog or reduce the volume of  
fluid flow from an inlet to an outlet.

1 Yet another object of the invention is to avoid the use of projections on a closure for an inlet, whereby a Luer fitting can open an inlet channel without the need for engaging one or more projections on a closure.

5 A further object of the invention to enhance the control that can be achieved over fluid flow. A related object is to enhance flow control where fluid infusion or combination is to take place.

10 An important object of the invention is to eliminate the need for needle usage at injection sites, while permitting needle usage if that is desired. A related object is to maintain sterility at injection sites that are operated without needles, while simultaneously permitting such sites to be used with needles if necessary.

15 An additional object of the invention is to improve the performance of valves for infusion, injection, aspiration and control of fluid flow.

#### SUMMARY OF THE INVENTION

20 In accomplishing the foregoing and related objects the invention provides a flow control device with an inlet for the flow of fluid, an outlet connected to the inlet and disposed to serve as a conduit for flow from the inlet and a movable member having a normally open slotted and compressible head for sealing the inlet. The moveable member also has a flexible body which may include a closed channel and extends to the outlet for permitting flow through the head to the outlet when the inlet is unsealed.

25 The flexible body may include outwardly tapered and slotted side walls forming legs which promote the sealing of the inlet and return the head to its sealing position.

30 In accordance with one aspect of the invention, the inlet extends to a tapered bore which is spaced from the movable member, and the slot of the head is opened when the head is moved to the tapered bore. The tapered bore can extend to a second bore within which the flexible body is expandable laterally with respect to the axis of the outlet. The flexible body can be rectangular in cross-section and spaced from the second bore.

1 In accordance with another aspect of the invention,  
activation of the movable member can be accomplished  
externally to the flow control device, for example, by the  
tip of a Luer taper which seals on the top surface of the  
5 head as it depresses the head of the moveable member in  
order to allow the opening of the slot and unseal the inlet.

In accordance with a further aspect of the  
invention, a closed channel member extends into the outlet  
and is moveable therein. The flexible body can include the  
10 closed channel member and a spring, of metal or plastic, for  
biasing, so that the removal of a force causing the closed  
channel member to move into the outlet causes the closed  
channel member to return to its equilibrium position.

The slot of the head advantageously is in the form  
15 of a multi-sided geometric figure with opened segments when  
the head is in a non-sealing position. At the entrance to  
the inlet, the head may also have a depressed surface that  
is complementary to the tip of a Luer taper.

In a method of fabricating a flow control device,  
20 the steps include (a) molding a rectangular inlet member  
having an axis of flow, an inlet, a coaxial seat beyond the  
inlet, and an expansion chamber beyond the coaxial seat; (b)  
molding a rectangular outlet member which complements the  
inlet member and has a rectangular coaxial support; (c)  
25 inserting an apertured, expandable and rectangular control  
member into the inlet member; and (e) joining the outlet  
member to the inlet member with the expandable control  
member against the outlet support.

#### DESCRIPTION OF THE DRAWINGS

30 Fig. 1A is a scale view of one side of a flow-  
control valve in accordance with the invention;

Fig. 1B is an enlarged sectional view of the flow-  
control valve of Fig. 1A in its closed valve position;

35 Fig. 2A is an enlarged sectional view of the flow-  
control valve of Fig. 1A in its "operational flow" position  
with an external pressure member;

Fig. 2B is a sectional view of the flow-control  
valve of Fig. 2A taken along the lines B-B;

1           Fig. 2C is a bottom view of the flow-control valve  
of Fig. 2A;

          Fig. 3A is a scale view of the other side of the  
flow-control valve of Fig. 1A in accordance with the  
5       invention;

          Fig. 3B is an enlarged sectional view of the flow-  
control valve of Fig. 3A in its closed valve position;

          Fig. 4A is a sectional view of the flow-control  
valve of Fig. 3A taken along the lines 4A-4A;

10          Fig. 4B is a top view of the flow control valve of  
Fig. 3A;

          Fig. 5A is a scale view of one side of a flow-  
control plug for the valve of Fig. 1A;

          Fig. 5B is an enlarged view of the flow-control plug  
15       of Fig. 5A in its "pre-operation" condition;

          Fig. 5C is an enlarged sectional view of the flow-  
control plug of Fig. 5B in its "pre-operation" condition;

          Fig. 5D is a bottom view of the flow-control plug of  
Figs. 5B and 5C;

20          Fig. 6A is a scale view of the other side of the  
flow-control plug for the valve of Fig. 1A

          Fig. 6B is an enlarged view of the flow-control plug  
of Fig. 6A in its "pre-operation" condition;

          Fig. 6C is a sectional view of the flow-control plug  
25       of Fig. 6B in its "pre-operation" condition taken along the  
lines 6C-6C;

          Fig. 6D is a sectional view of the flow-control plug  
of Fig. 6B taken along the lines 6D-6D;

          Fig. 6E is a sectional view of the flow-control plug  
30       of Fig. 6B;

          Fig. 7A is a cross-sectional view of an alternative  
flow-control valve in accordance with the invention;

          Fig. 7B is an enlargement showing details for the  
spring-loaded plug of Fig. 7A;

35          Fig. 8A is a cross-sectional view of an alternative  
to the flow-control valve of Fig. 7A in accordance with the  
invention;

          Fig. 8B is an enlargement showing alternative  
details for the plug of Fig. 8A;

- 1           Fig. 8C is a cross-sectional view of the plug of  
Fig. 8B taken along the lines 8C-8C;  
          Fig. 8D is a cross-sectional view of the plug of  
Fig. 8B taken along the lines 8D-8D;  
5           Fig. 9A is an enlarged end view of an alternative  
tip for the plugs of Figs. 1A through 8D;  
          Fig. 9B is a partial cross-section of the tip of  
Fig. 9A taken along the lines 9B-9B;  
          Figs. 10A through 10E are end views of alternative  
10          tips for plugs in accordance with the invention;  
          Fig. 11A is an enlarged end view of an alternative  
tip for the plugs of Figs. 1A through 8D; and  
          Fig. 11B is a partial cross-section of the tip of  
Fig. 11A taken along the lines 11B-11B.

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#### DETAILED DESCRIPTION

- With reference to the drawings, Figs. 1A and 3A are  
scale views of different sides of a flow-control valve 10 in  
accordance with the invention. The valve 10 is rectangular  
in cross-section having the specific configuration described  
20          in detail below, with Fig. 1A showing the longer side and  
Fig. 3A showing the shorter side.

- In Fig. 1B, which is an enlarged sectional view, the  
flow-control valve of Fig. 1A is shown in its "pre-loaded"  
condition with its inlet 11 sealed by the head 21 of a  
25          depressible plug 20. As indicated in Fig. 1B, the head 21  
of the plug 20 has a closed slot S. In addition, the valve  
10 has an outlet 12 connected to the inlet 11 and disposed  
to serve as a conduit for the throughflow of fluid that is  
applied at the inlet 11, thru the slot S.

- 30          The depressible plug or movable member 20 (as shown  
further in Figs. 5A through 6E) has a flexible head 21 which  
seals the inlet 11 and extends to a flexible body 22 for  
controlling flow by the outward flexing of the body 22 when  
the head 21 is depressed as indicated in Fig. 2A.

- 35          In effect, the plug 20 forms a bell-shaped member  
with a hollow head 21 and a slotted body 22. The base of  
the body 22 terminates in a circumferential rectangular base  
24. The rectangularity avoids twisting during compression.

1           In the flow control device 10, the movable plug 20,  
together with the head 21 and the flexible body 22, extends  
between the inlet 11 and the outlet 12. The flexible body  
22 is expandable laterally with respect to the vertical axis  
5   A of the outlet channel 12 in order to create spring  
pressure during opening and closing of slot S.  
Consequently, the upper housing 13 has an enlarged expansion  
chamber 13-1. In addition, the housing 13 has a neck 13-2  
with exterior Luer threads 13-t and an inwardly tapered bore  
10 13-b1 beyond an interior cylindrical rim 13-r. Extending  
from the inwardly tapered bore 13-b1 is a cylindrical bore  
13-c which, in turn, extends to rectangular walls 13-b2 of  
the expansion chamber 13-1. A horizontal wall 13-b3  
connects the cylindrical bore 13-c to the rectangular walls  
15 13-b2.

A shoulder 23 of the plug 20 engages the horizontal  
wall 13-b3 proximate the bore 13-c of the expansion chamber  
13-1. The head 21 seals the inlet 11 by being compressed  
against the inwardly tapered bore 13-b1, and cylindrical rim  
20 13-r, as described below. The head 21 remains in sealing  
contact with the tapered bore 13-b1 of the neck 13-2, and  
then with the bore 13-c, as the plug is depressed.

However, when the bore 13-c at the end of the  
tapered bore 13-b1 is reached, the slot S opens, as shown in  
25 Figs. 2A and 2B. Within the expansion chamber 13-1, the two  
legs of the body 22 can be spaced from the rectangular walls  
13-b2, as shown in Fig. 4A.

For the embodiment of Figs. 1B, 2A and 3B, the head  
21 of the plug 20 has an upper slot 21-s so that when a Luer  
30 tip, such as the tip 31 of Fig. 2A is threaded on the neck  
13-2 it seals circumferentially on top of plug 20 and there  
is no impediment to flow from the interior of the tip 31.  
This embodiment is particularly useful for relative low  
pressure infusion of fluids, e.g. by gravity flow from a  
35 saline bag (not shown). It is to be noted that because of  
the slot 21-s, pressure against the outer surface of the  
head 21 does not cause a collapse of material which could  
block the tip 31.

1           The Luer tip 31 thus permits activation of the  
control plug by a member external to the flow control device  
10 since the plug 20 is seated in the inlet 11 and can be  
depressed from its compressed seal position to the bore  
5 13-c. In effect the control is by a bell-shaped member with  
its upper portion sealing the inlet, and walls straddling  
the outlet. The walls are extended legs 22-1 and 22-2 which  
are bowed under pressure in the axial direction of the  
outlet channel 12. The slotted walls 22-1 and 22-2 are  
10 flexed or buckled under pressure. They extend from the head  
21 sealing the inlet 11 to a base 14-1 of a lower body 14  
encircling the outlet channel 12.

Fig. 2B is a sectional view of the flow-control  
valve of Fig. 2A taken along the lines 2B-2B, while Fig. 2C  
15 is a bottom view of the flow-control valve of Fig. 2A.  
Fig. 3B is an enlarged sectional view of the flow-control  
valve of Fig. 3A in its closed position, while Fig. 4A is a  
sectional view of the flow-control valve of Fig. 3A taken  
along the lines 4A-4A, and Fig. 4B is a top view of the  
20 flow-control valve of Fig. 3A.

The component elements 13 and 14 are locked together  
by snap action, but can be joined, for example, by  
ultrasonic welding. The valves of the invention promote  
sterility by providing ease of accessibility. Prior art  
25 valves with recessed stoppers allow antimicrobial agents to  
accumulate in puddles on the tops of stoppers. Particulate  
matter may also collect on recessed tops.

Fig. 5A is a scale view of one side of a flow-  
control plug 20 for the valve 10 of Fig. 1A, and Fig. 5B is  
30 an enlarged view of the flow-control plug of Fig. 5A in its  
"pre-installation" condition, while Fig. 5C is an enlarged  
sectional view of the flow-control plug of Fig. 5B in its  
"pre-installation" condition with a star-shaped slot S.  
Fig. 5D is a bottom view of the open, star-shaped slot S in  
35 the flow-control plugs of Figs. 5B and 5C.

Fig. 6A is a scale view of the other side of the  
flow-control plug for the valve of Fig. 1A, and Fig. 6B is  
an enlarged view of the flow-control plug of Fig. 6A showing  
the open star-shaped slot S in its phantom "pre-

-10-

1 installation" condition. Fig. 6C is a sectional view of the  
flow-control plug of Fig. 6B in its "pre-installation"  
condition taken along the lines 6C-6C showing the open star-  
shaped slot S, and Fig. 6D is a sectional view of the flow-  
5 control plug of Fig. 6B taken along the lines 6D-6D, while  
Fig. 6E is a sectional view of the flow-control plug of Fig.  
6B.

An alternative flow control plug 70 in accordance  
with the invention is shown in Fig. 7A. The plug 70 is used  
10 with the same general outer structure as the device 10 of  
Fig. 1A. However the plug 70 has a closed channel 72 which  
extends from a head 71 (like the head 11 of Fig. 1A) and is  
freely moveable into the outlet 12 when the head is  
depressed. In order to restore the plug to its equilibrium  
15 condition when pressure to the head is removed, the plug 70  
includes a spring 73, which is metallic in Figs. 7A and 7B.  
A non-metallic, e.g. plastic spring, comprising resilient  
legs 83-1 and 83-2 is shown in Fig. 8A. Fig. 8B shows an  
alternative-shaped plug with a head 81 and a spring portion  
20 84, also comprising resilient legs 83-1 and 83-2. It will  
be appreciated that a metallic spring does not cause  
contamination in the embodiment of Figs. 7A and 7B because  
the closed channel prevents fluid contact with the spring.

In order to facilitate the sealing of the head 11 it  
25 desirably takes the modified form 91 shown in Figs. 9A and  
9B with side grooves 91-g. In addition the open, star-  
shaped slot S-1 of Fig. 9A is six-pointed, with segments to  
facilitate complete closure of the slot S-1 when the valve  
is sealed. Still other forms for the slot S are illustrated  
30 by the open, slots S-2 through S-6 of Figs. 10A through 10E.  
In addition the heads of Figs. 10B and 10E are square, as  
shown in Fig. 10E, or rectangular, as shown in Fig. 10D.  
The ring 93 defined by the phantom lines 95, 96 indicates  
the region of contact between an externally activating male  
35 Luer and the top surface of the head 91.

A square plug 100 similar to that of Fig. 10, except  
for having an open, star-shaped slot S' with arcuate sides,  
is shown in Fig. 11A, and is illustrated in Fig. 11B, in  
partial cross-section taken along the lines B-B in Fig. 11A.

-11-

1 This form of plug achieves the same kind of sealing effect  
that is achieved by use of the grooves 91-g in Figs. 9A and  
9B. The ring 102 defined by the phantom lines indicates the  
region of contact between the externally activating male  
5 Luer and the top surface of the square plug 100.

It will be understood that the foregoing embodiments  
are illustrative only and that modifications and adaptations  
of the invention may be made without departing from its  
spirit and scope as defined in the appended claims.

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1     What is claimed:

1. A flow control device comprising:  
an inlet for the flow of fluid;  
an outlet connected to said inlet and disposed with  
5     respect thereto to serve as a conduit for flow from said  
inlet; and

slidable movable means having a normally open  
slotted and compressible head for sealing said inlet,  
wherein said inlet closes the slot from a completely open to  
10     a completely closed condition, and a flexible body including  
a channel extending to said outlet for permitting flow  
through said head to said outlet when said inlet is  
unsealed;

said flexible body having outwardly tapered and  
15     slotted side walls forming legs for providing a return force  
for returning said head into position sealing said inlet.

2. A flow control device in accordance with claim  
1, wherein said inlet extends to a tapered bore which is  
spaced from said movable means, and the slot of said head  
20     returns to its completely open condition when said head is  
moved from said inlet to said tapered bore.

3. A flow control device in accordance with claim  
2, wherein said tapered bore extends to a second bore within  
which said flexible body is expandable outwardly with  
25     respect to the axis of said outlet.

4. A flow control device in accordance with claim  
3, wherein said flexible body is spaced from said second  
bore to permit expansion and contraction during the opening  
and closing of said slot.

5. Apparatus as defined in claim 1, further  
30     comprising means for permitting the activation of said  
movable means by a member external to the flow control  
device by engaging and depressing said head into said  
tapered bore, opening said slot, wherein the external member  
35     does not penetrate the slot of said head.

6. Apparatus as defined in claim 5, wherein said  
legs provide the return force returning said head into its  
sealing position, when the external member is removed.

1           7. Apparatus as defined in claim 1, wherein an inner flow passage extends continuously from said slot to said outlet.

5           8. Apparatus as defined in claim 1, wherein the slot of said head is in the form of a multi-sided geometric figure with opened segments when said head is in a non-sealing position.

10          9. Apparatus as defined in claim 5, wherein said external member is a tip of a Luer taper and said head has a depressed surface that is sealingly complementary to and non-penetrable by the tip of the Luer taper at the entrance to said inlet.

15          10. Apparatus of claim 6, wherein said flexible body has a rectangular base sitting in a rectangular well proximate said outlet.

20          11. Apparatus of claim 10, wherein said flexible body comprises slotted walls coupled to said base, straddling the channel, said walls flexing when said head is moved from said inlet to said tapered bore, opening said slot, providing the return force.

25          12. A flow control device comprising  
an inlet for the flow of fluid;  
an outlet connected to said inlet and disposed with respect thereto to serve as a conduit for flow from said inlet; and

30          movable means having a normally open slotted and compressible head for sealing said inlet, and a flexible body including an inner flow passage engaging said outlet for permitting flow through said head to said outlet when said inlet is unsealed;

        a spring biasing the movable means;  
        wherein said movable means is movable from an equilibrium position in said inlet, sealing said inlet, to a position opening said inlet by a force, whereby the removal of the force causes said spring to return said movable means to its equilibrium position sealing said inlet.

35          13. A flow control device comprising  
an inlet for the flow of fluid;

1           an outlet connected to said inlet and disposed with  
respect thereto to serve as a conduit for flow from said  
inlet; and

5           slidable movable means having a normally open  
slotted and compressible head for sealing said inlet, and a  
flexible body including an inner flow passage extending to  
said outlet for permitting flow through said head to said  
outlet when said inlet is unsealed;

10          said flexible body comprising outwardly tapered and  
slotted outer walls forming legs for providing a return  
force on said head when said flexible body is compressed.

14. A flow control device comprising:

an inlet for the flow of fluid;

15          an outlet connected to said inlet and disposed with  
respect thereto to serve as a conduit for flow from said  
inlet; and

20          slidable movable means having a slotted and  
compressible head for sealing said inlet, wherein said inlet  
closes the slot from a completely open to a completely  
closed condition, and a flexible body depending from said  
head and including a channel extending to said outlet for  
permitting flow through said head to said outlet when said  
inlet is unsealed;

25          wherein said inlet extends to a tapered bore which  
is spaced from said movable means, and the slot of said head  
is opened when said head is moved from said inlet to said  
tapered bore by a member external to the flow control device  
which engages and depresses said head into said tapered  
bore, opening said slot, and

30          said flexible body comprises outwardly tapered and  
slotted side walls forming legs which are compressed when  
said head is depressed, providing a return force for  
returning said head into position sealing said inlet, when  
the external member is removed.

35          15. Apparatus of claim 15, further comprising a  
rectangular well proximate said outlet, wherein said  
flexible body has a rectangular base sitting in said  
rectangular well.

1           16. The method of fabricating a flow control device which comprises the steps of:

          (a) molding an inlet member having an axis of flow, an inlet, a coaxial seat beyond said inlet, and an expansion  
5   chamber beyond said coaxial seat;

          (b) molding an outlet member which complements said inlet member and has a coaxial support;

          (c) inserting an expandable control member, having, before insertion, an open slot, into said inlet member with  
10   respect to said seat; and

          (e) joining said outlet member to said inlet member with said control member therein and said slot closed.

          17. The method of claim 16, further including the step of molding said control member of an elastomeric  
15   material with an open slot.

          18. The method of claim 16, further including the step of molding said control member of an elastomeric material with an inner cylindrical shell extending from said open slot for movement into an outlet when said control  
20   member is depressed.

          19. A flow control device comprising:

          an inlet for the flow of fluid;

          an outlet connected to said inlet and disposed with respect thereto to serve as a conduit for flow from said  
25   inlet; and

          slidable movable means having a normally open slotted and compressible head for sealing said inlet, wherein said inlet closes said slot from a completely open to a completely closed condition, and a flexible body  
30   including a channel extending to said outlet for permitting flow through said head to said outlet when said inlet is unsealed;

          wherein the slot of said head is in the form of a multi-sided geometric figure with opened segments when said  
35   head is in a non-sealing position.

          20. The device of claim 19, wherein said flexible body comprises outwardly tapered and slotted side walls forming legs for providing a return force for returning said head into position sealing said inlet.

## AMENDED CLAIMS

[received by the International Bureau on 21 October 1997 (21.10.97);  
original claims 5-15 amended; remaining claims unchanged (5 pages)]

1. A flow control device comprising:

an inlet for the flow of fluid;

an outlet connected to said inlet and disposed with respect  
thereto to serve as a conduit for flow from said inlet; and

slidable movable means having a normally open slotted and  
compressible head for sealing said inlet, wherein said inlet closes the slot  
from a completely open to a completely closed condition, and a flexible body  
including a channel extending to said outlet for permitting flow through said  
head to said outlet when said inlet is unsealed;

said flexible body having outwardly tapered and slotted side  
walls forming legs for providing a return force for returning said head into  
position sealing said inlet.

2. A flow control device in accordance with claim 1, wherein  
said inlet extends to a tapered bore which is spaced from said movable  
means, and the slot of said head returns to its completely open condition  
when said head is moved from said inlet to said tapered bore.

3. A flow control device in accordance with claim 2, wherein  
said tapered bore extends to a second bore within which said flexible body is  
expandable outwardly with respect to the axis of said outlet.

4. A flow control device in accordance with claim 3, wherein  
said flexible body is spaced from said second bore to permit expansion and  
contraction during the opening and closing of said slot.

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5. A flow control device in accordance with claim 4, further comprising means for permitting the activation of said movable means by a member external to the flow control device by engaging and depressing said head into said tapered bore, opening said slot, wherein the external member does not penetrate the slot of said head.

6. A flow control device in accordance with claim 5, wherein said legs provide the return force returning said head into its sealing position, when the external member is removed.

7. A flow control device in accordance with claim 1, wherein an inner flow passage extends continuously from said slot to said outlet.

8. A flow control device in accordance with claim 1, wherein the slot of said head is in the form of a multi-sided geometric figure with opened segments when said head is in a non-sealing position.

9. A flow control device in accordance with claim 5, wherein said external member is a tip of a Luer taper and said head has a depressed surface that is sealingly complementary to and non-penetrable by the tip of the Luer taper at the entrance to said inlet.

10. A flow control device in accordance with claim 6, further comprising a well, wherein said second bore extends to said well, said well defining said outlet and being rectangular as viewed along said axis, said flexible body has a rectangular cross section as viewed along said axis, a first end connected to said head, a second end, and a rectangular base connected to said second end, sitting in said rectangular well.

11. A flow control device in accordance with claim 10, wherein said flexible body comprises slotted walls coupled to said base, straddling the channel, said walls flexing when said head is moved from said inlet to said tapered bore, opening said slot and providing the return force.

12. A flow control device comprising:

an inlet for the flow of fluid;

an outlet;

a conduit connecting said inlet to said outlet enabling fluid flow from said inlet to said outlet;

a normally open slotted and compressible head movably disposed between said inlet and said outlet, wherein said inlet closes the slot when said head is in an equilibrium position in sealing engagement with said inlet, and the slot is opened when said head is moved out of sealing engagement with said inlet, allowing fluid to flow through said conduit; and

a spring biasing said head;

wherein said head is movable from the equilibrium position to a position opening said inlet by a force, whereby the removal of the force causes said spring to return said head to its equilibrium position sealing said inlet.

13. A flow control device comprising:

an inlet for the flow of fluid;

an outlet;

a conduit connecting said inlet to said outlet enabling fluid flow from said inlet to said outlet;

a slidable movable plug having a compressible head and a flexible body connected to said head, said head having a first position in sealing engagement with said inlet and a second position out of sealing engagement with said inlet, said head having a slot therethrough for permitting flow of fluid through said head when said head is in the second position; and

said flexible body comprising outwardly tapered and slotted outer walls forming legs for providing a return force on said head when said flexible body is compressed when said head is in the second position.

14. A flow control device comprising:

an inlet for the flow of fluid;

an outlet;

a conduit connecting said inlet to said outlet enabling fluid flow from said inlet to said outlet; and

a normally opened slotted and compressible head for sealing said inlet, wherein said inlet closes the slot from a completely open to a completely closed condition, and a flexible body depending from said head;

wherein said inlet extends to a tapered bore which is spaced from said movable means, and the slot of said head is opened when said head is moved from said inlet to said tapered bore by a member external to the flow control device which engages and depresses said head into said tapered bore, opening said slot, and

said flexible body comprises outwardly tapered and slotted walls forming legs which are flexed when said head is depressed, providing a

return force for returning said head into position sealing said inlet, when the external member is removed.

15. A flow control device in accordance with claim 15, further comprising a rectangular well proximate said outlet, wherein said flexible body has a rectangular base sitting in said rectangular well.

**FIG. 1A**

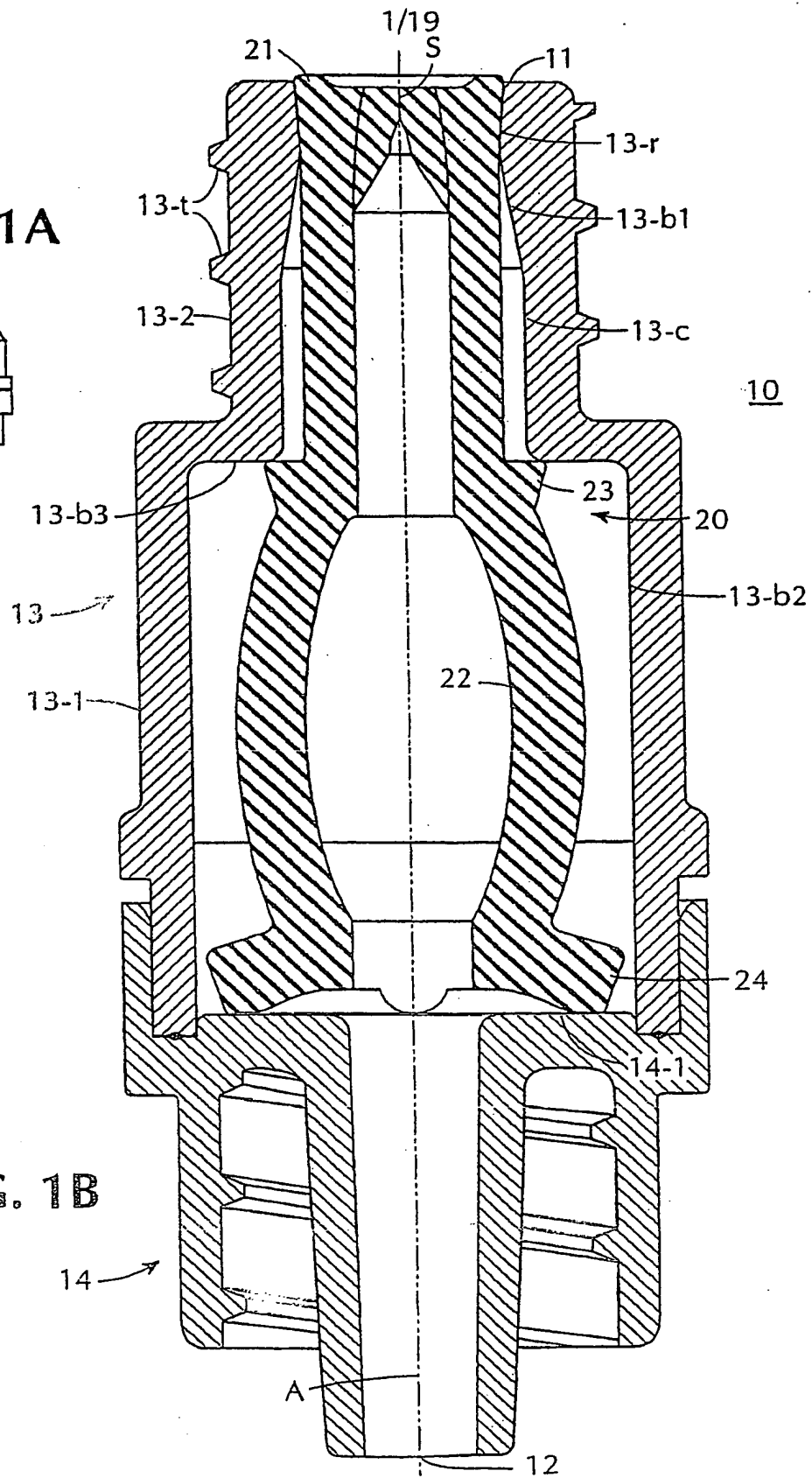
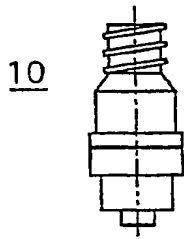
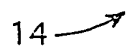


FIG. 1B



A

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FIG. 2B

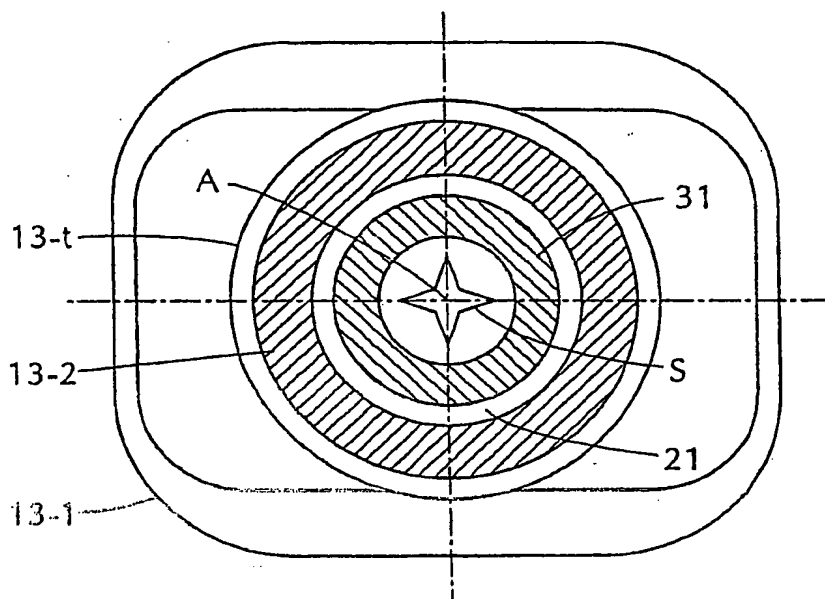


FIG. 2C

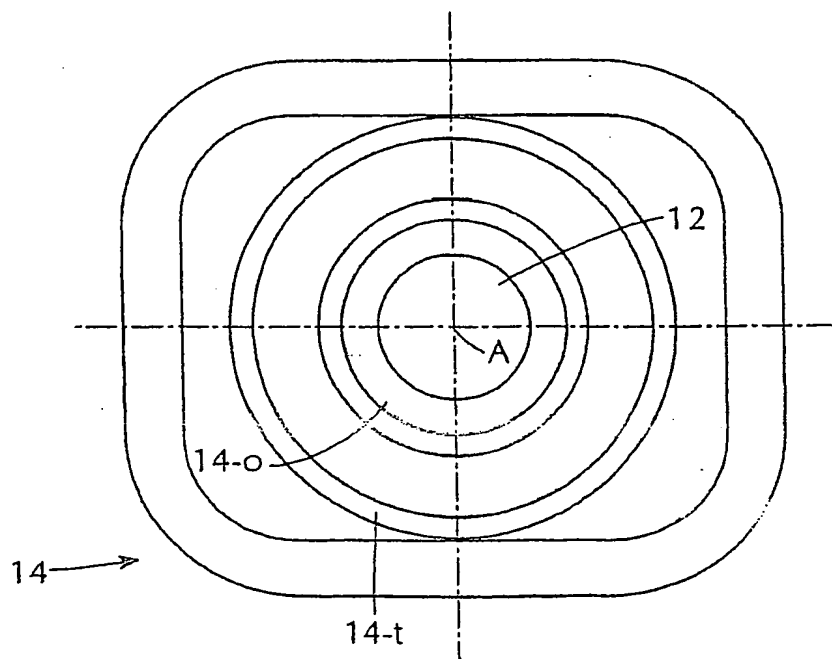


FIG. 3A

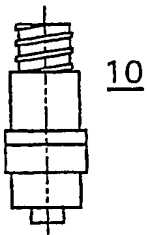
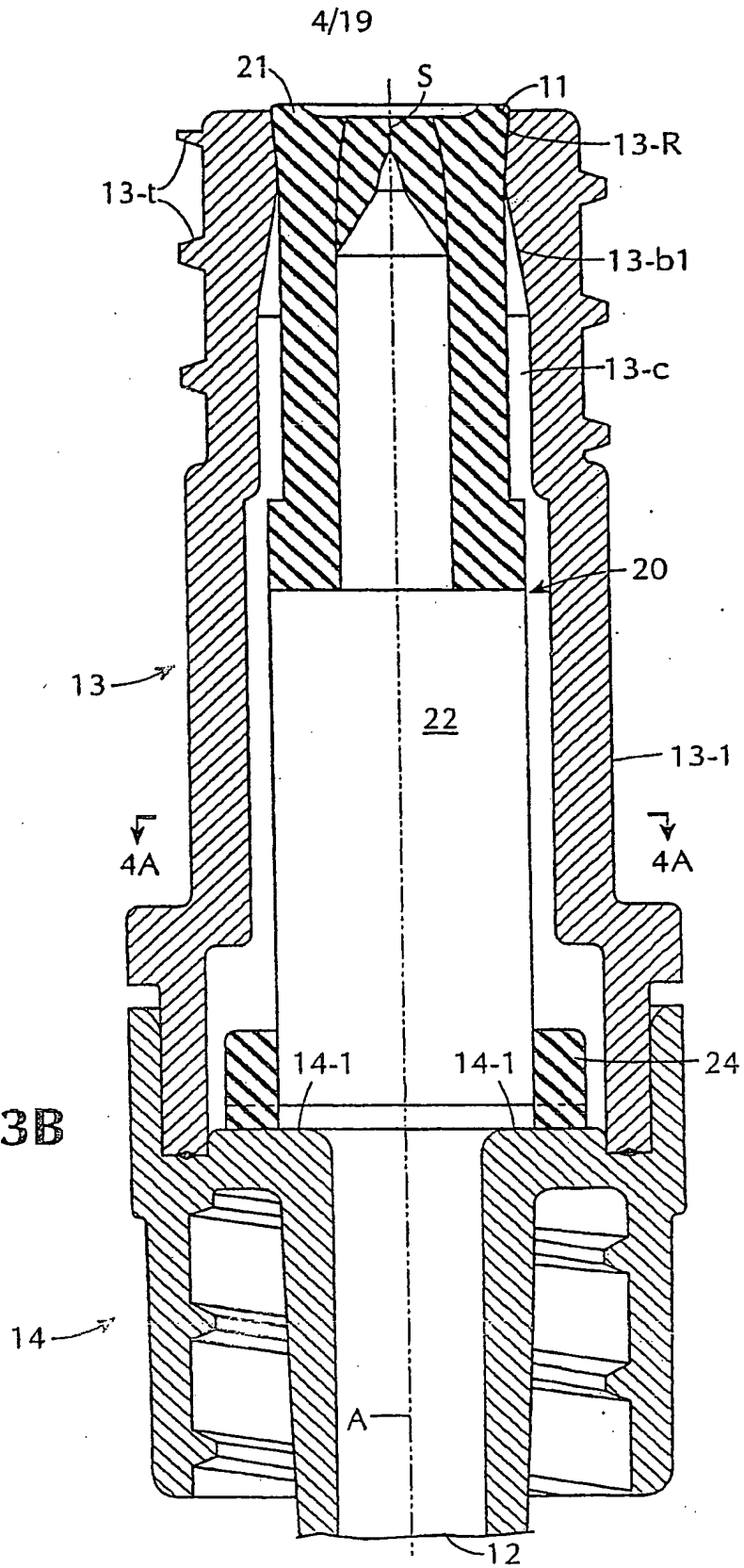


FIG. 3B



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FIG. 4A

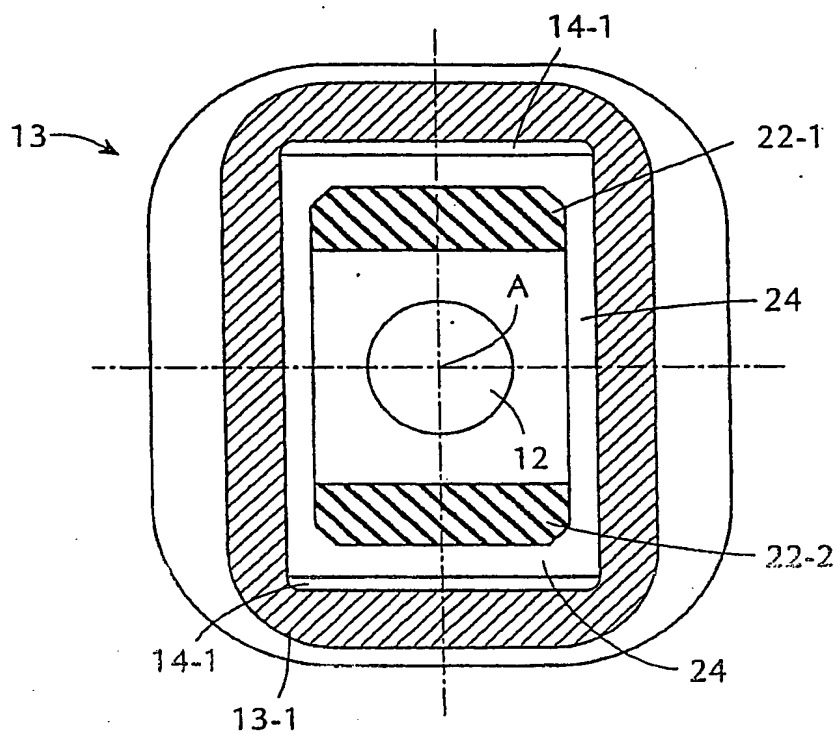
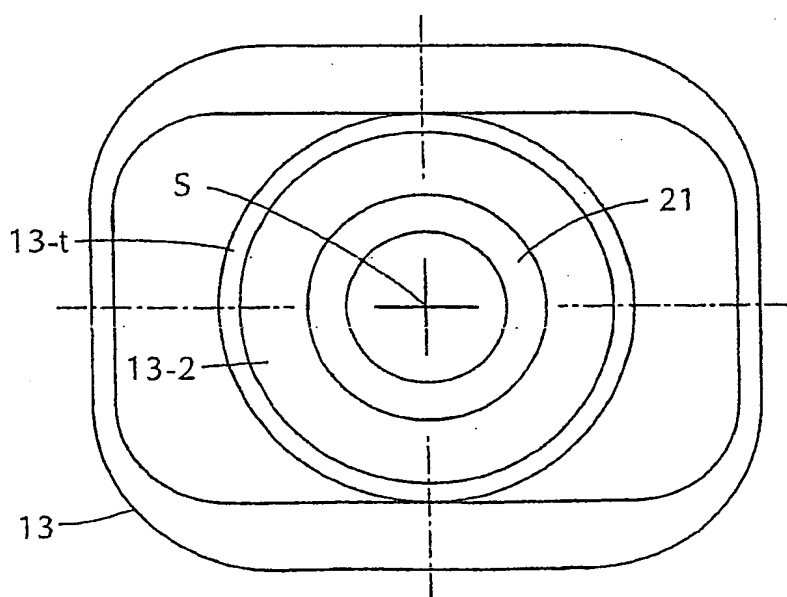


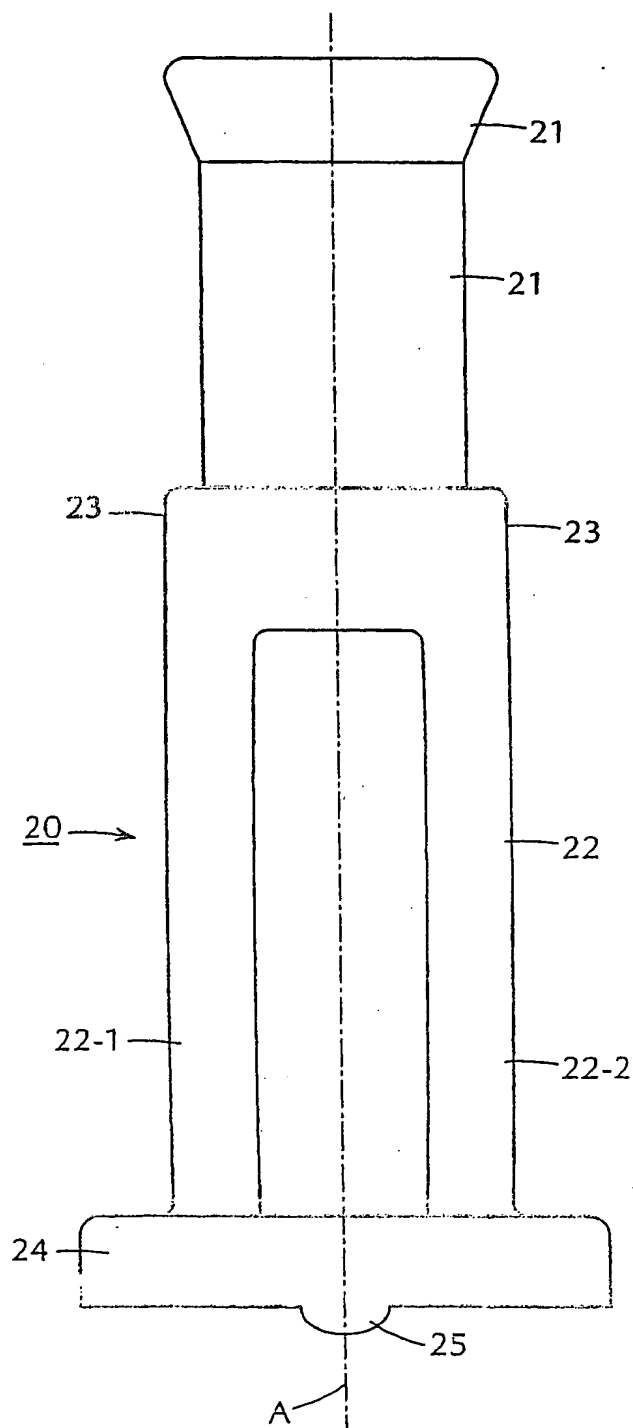
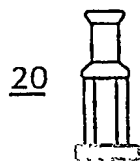
FIG. 4B



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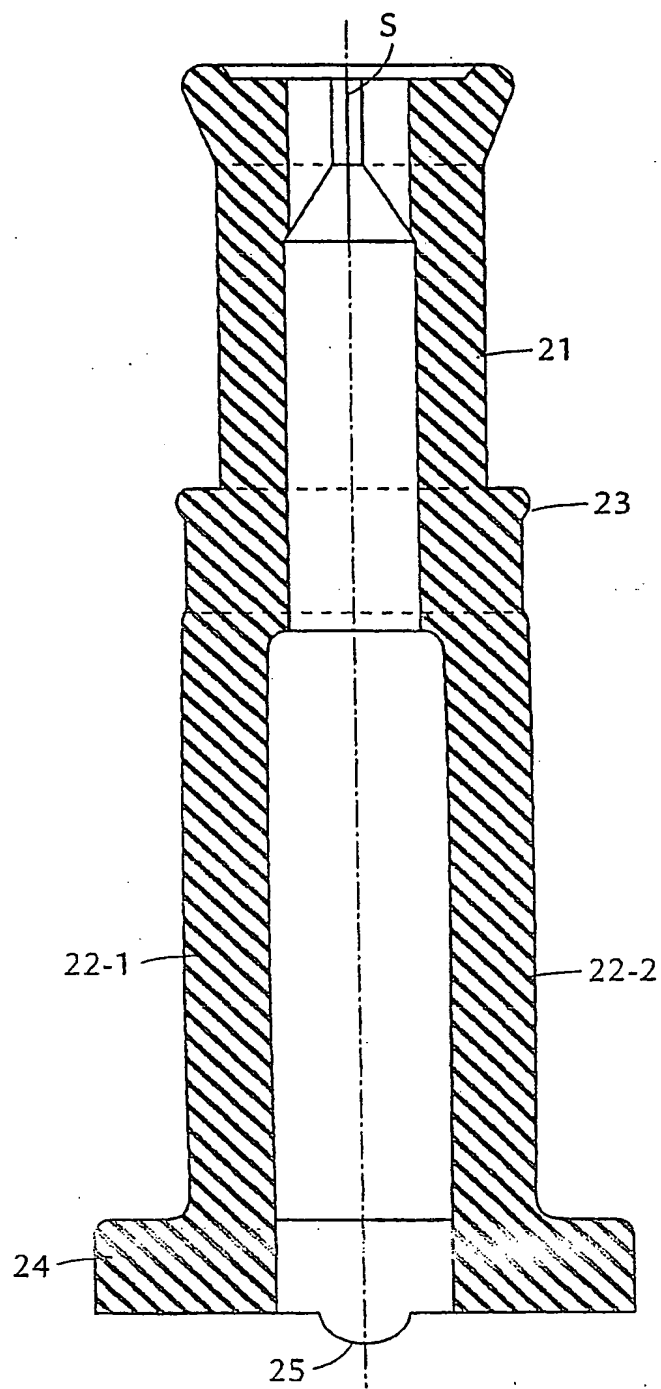
FIG. 5B

FIG. 5A

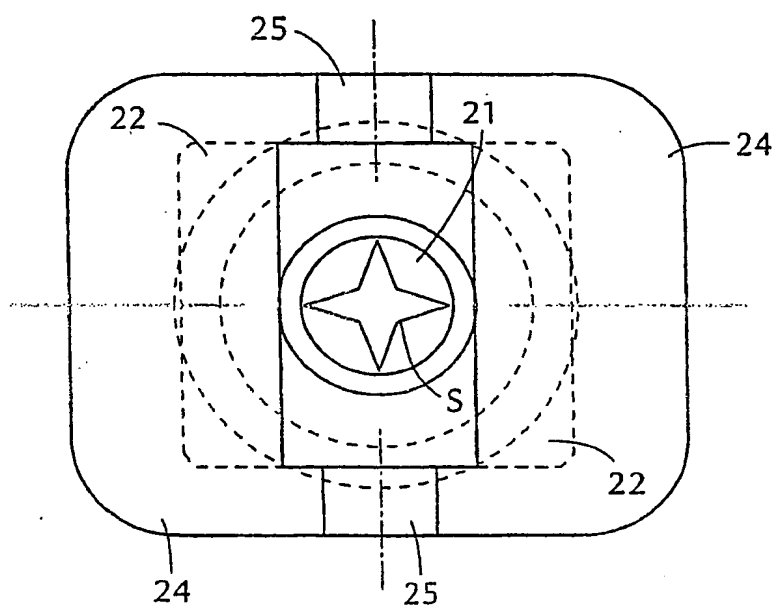


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FIG. 5C



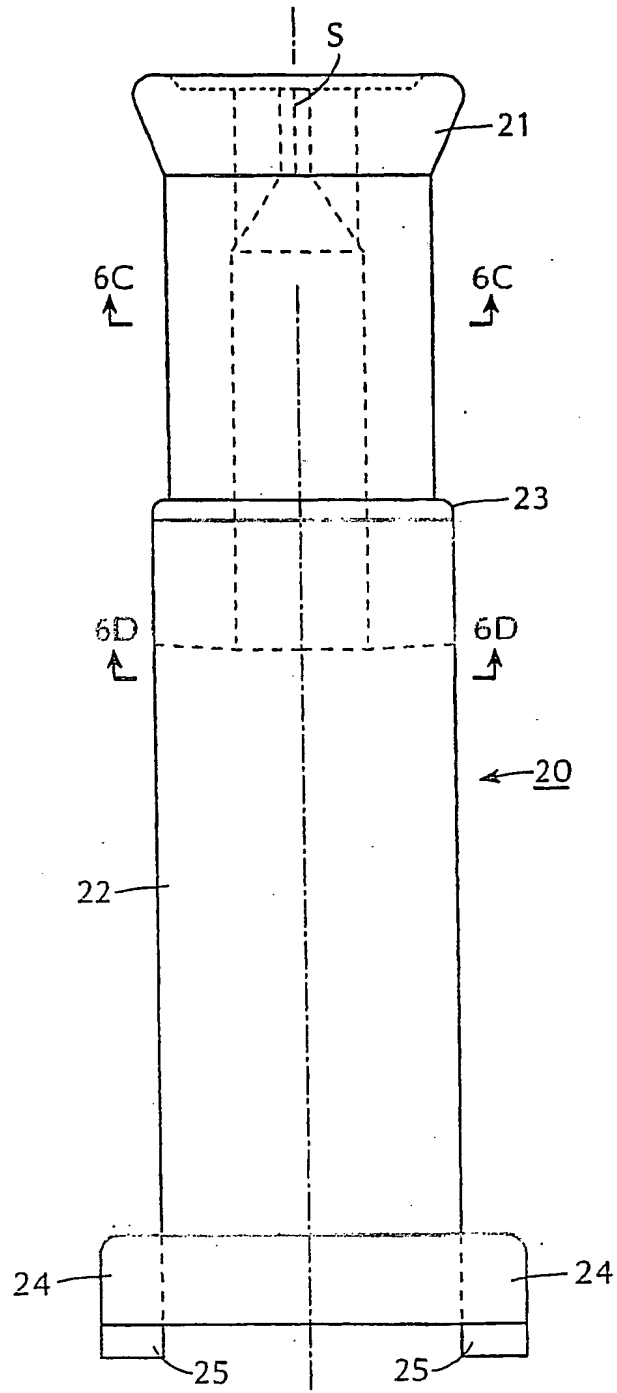
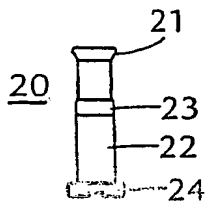
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**FIG. 5D**

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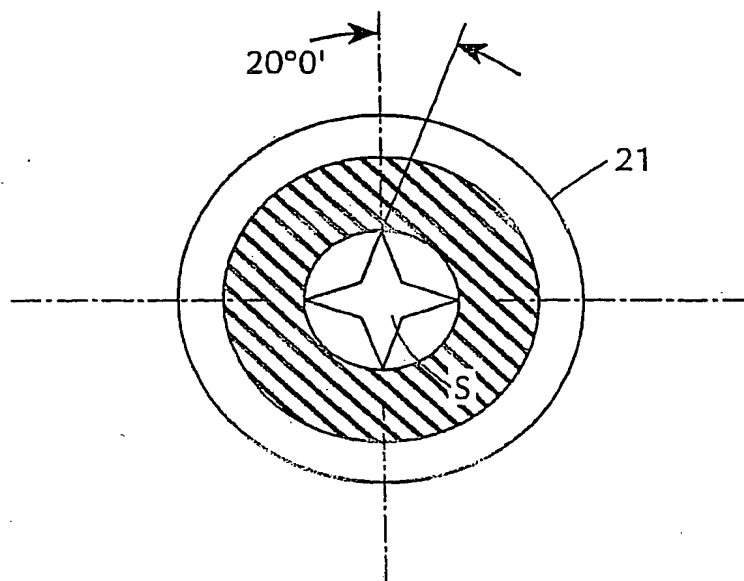
FIG. 6B

FIG. 6A

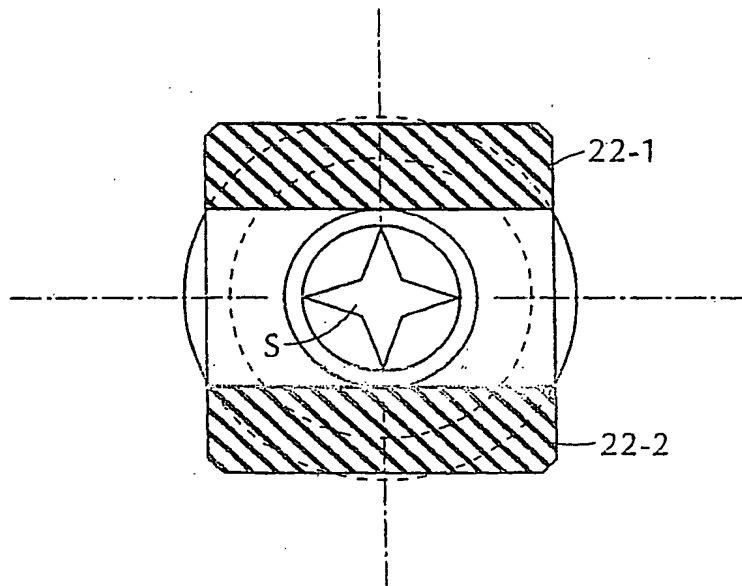


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**FIG. 6C**

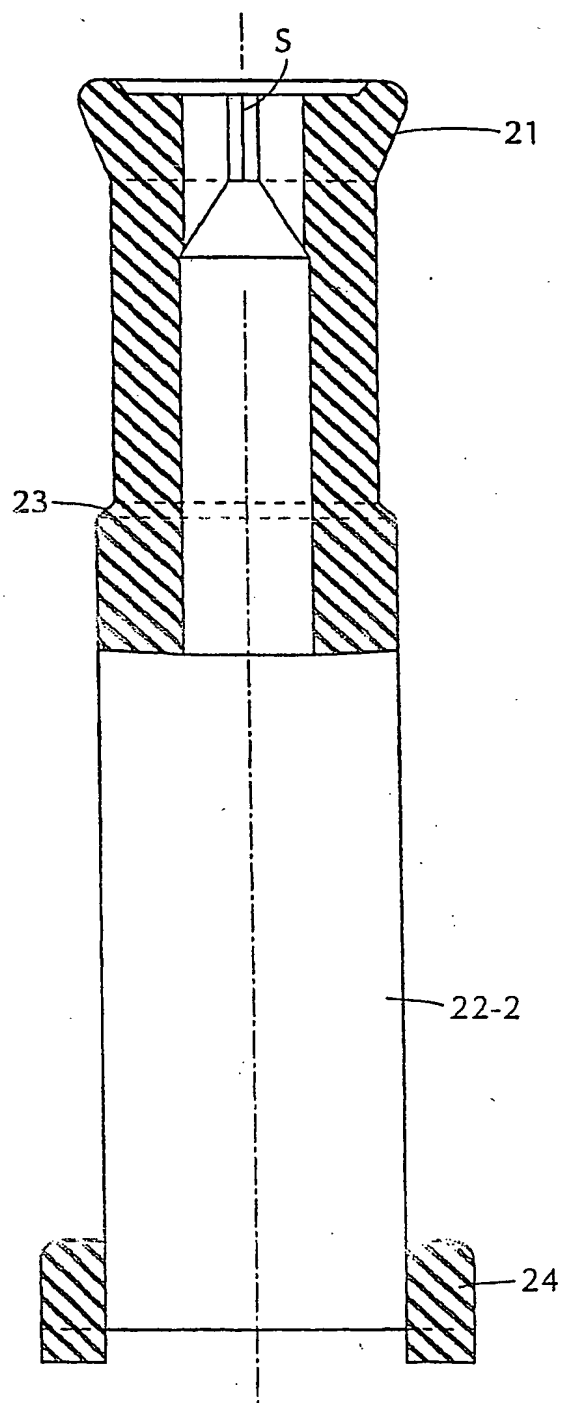


**FIG. 6D**



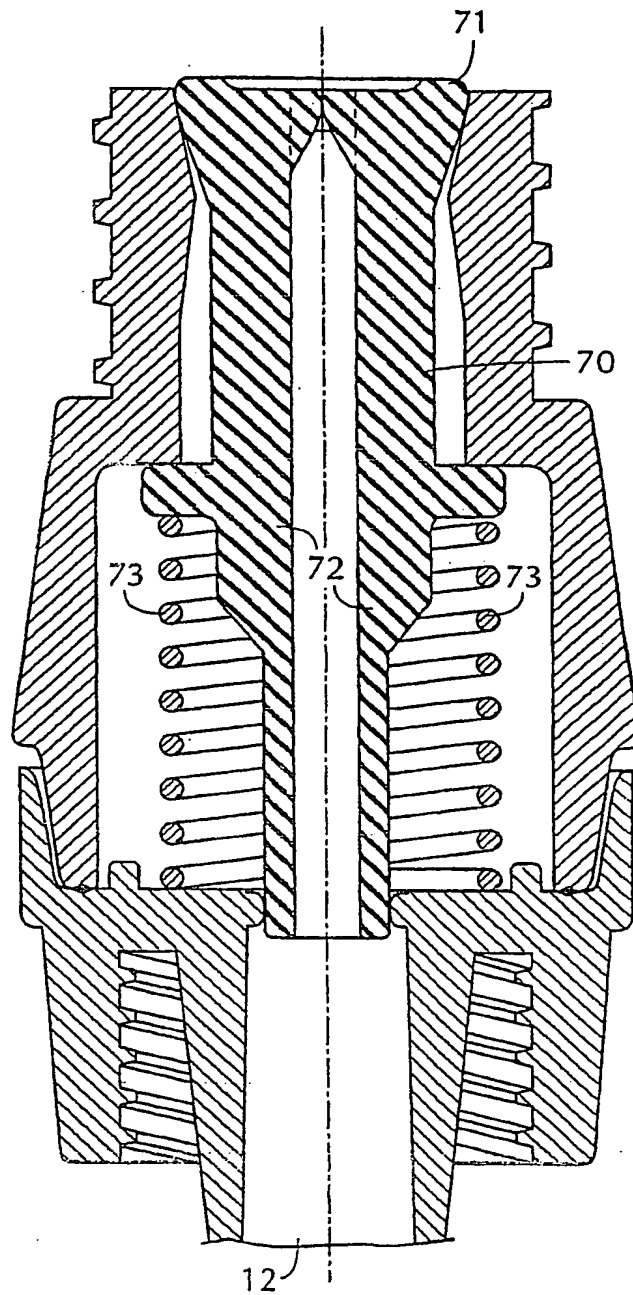
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FIG. 6E



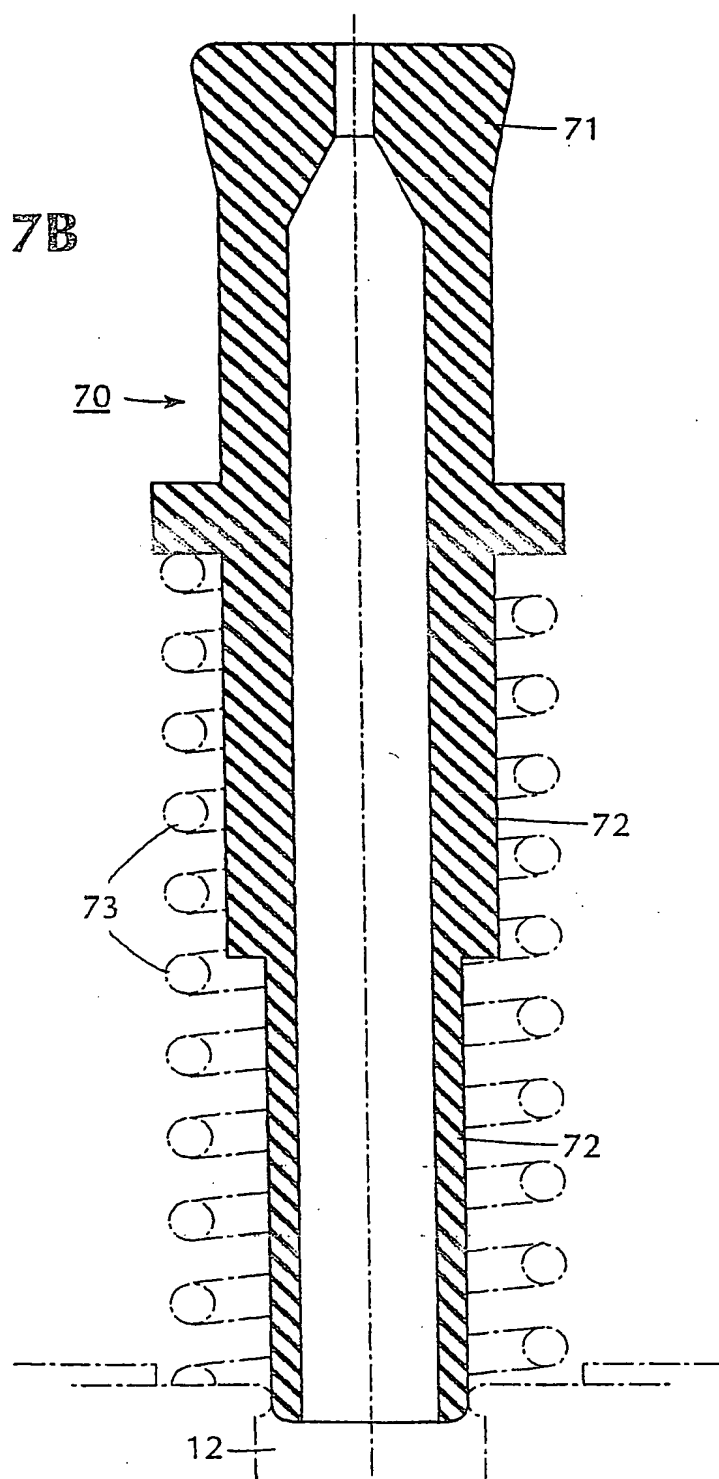
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FIG. 7A



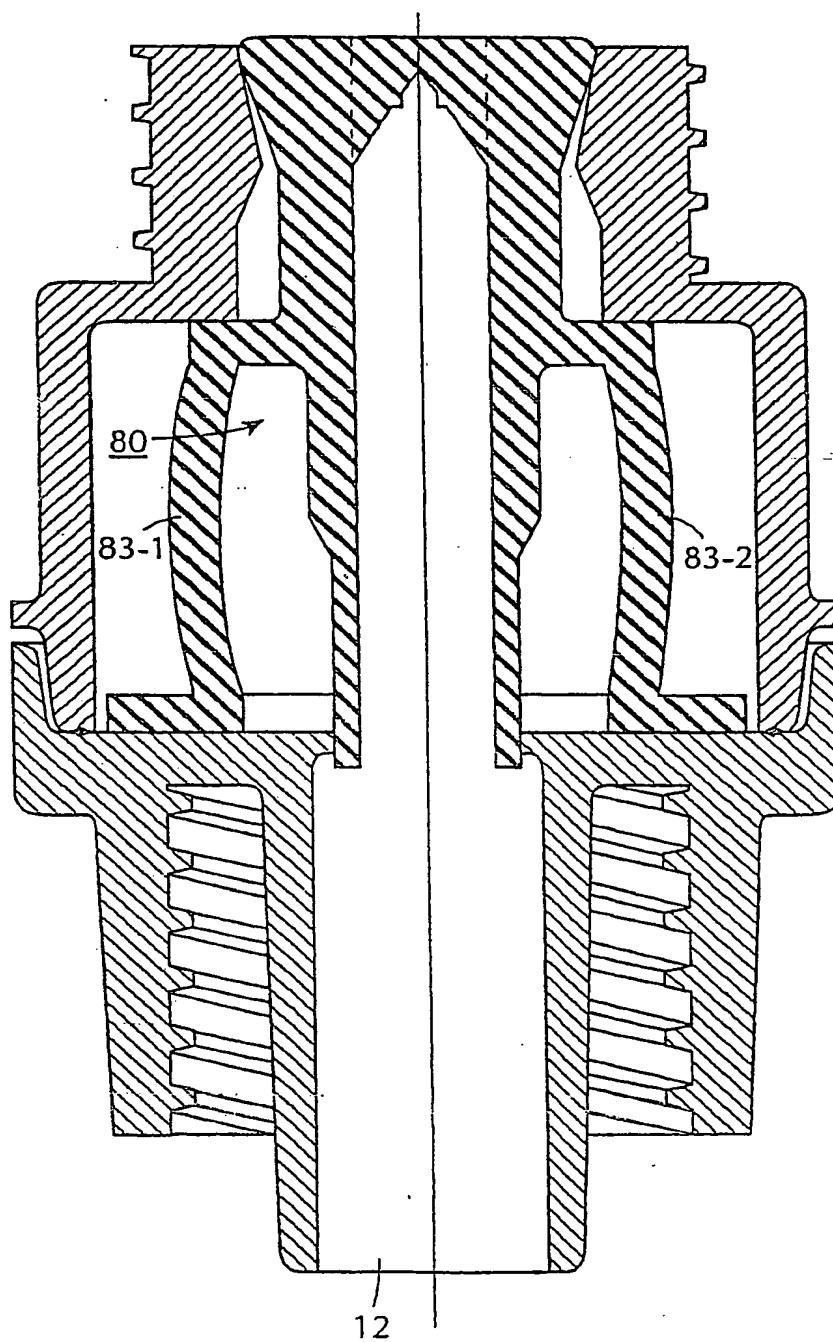
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FIG. 7B



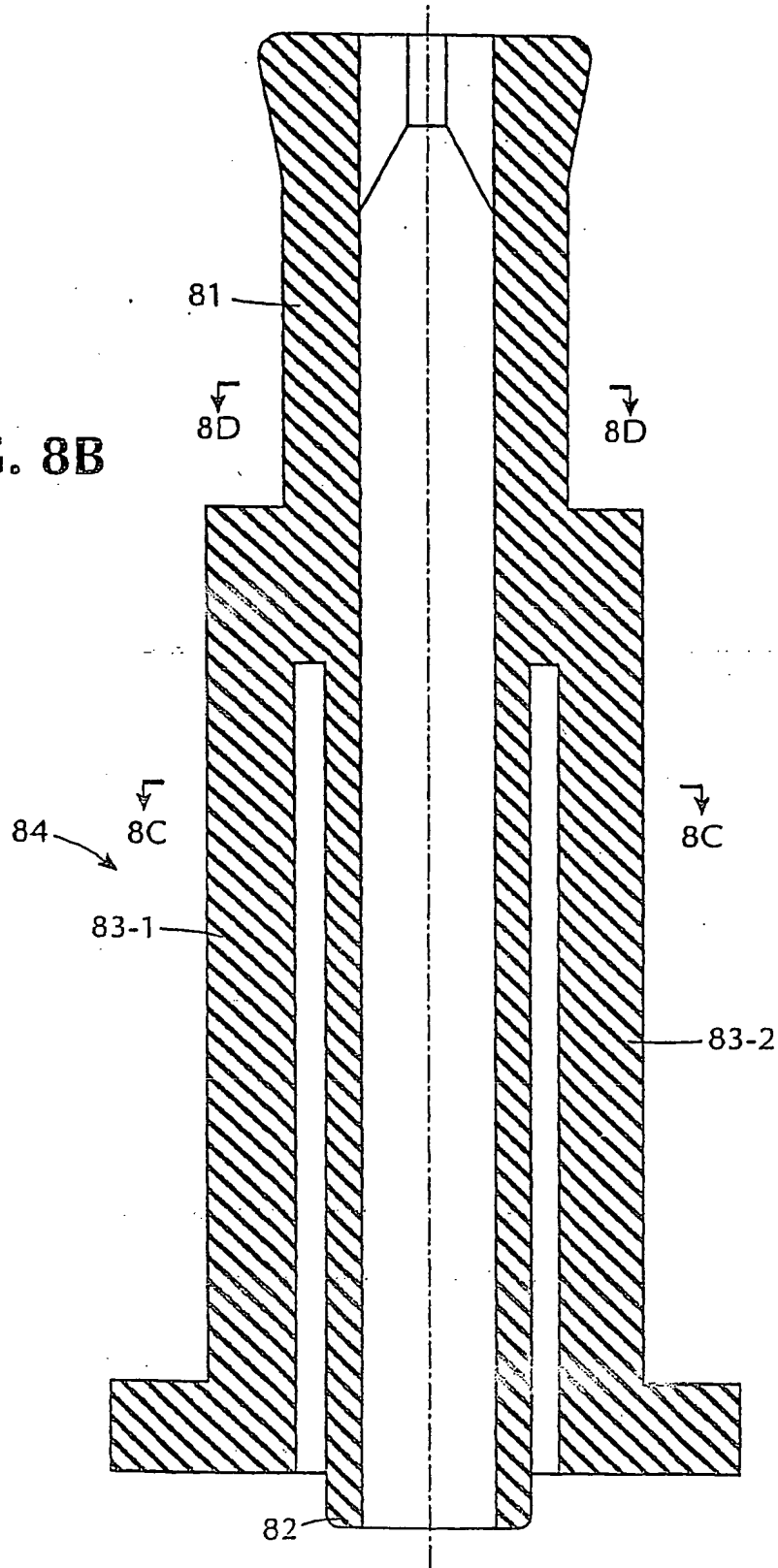
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FIG. 8A



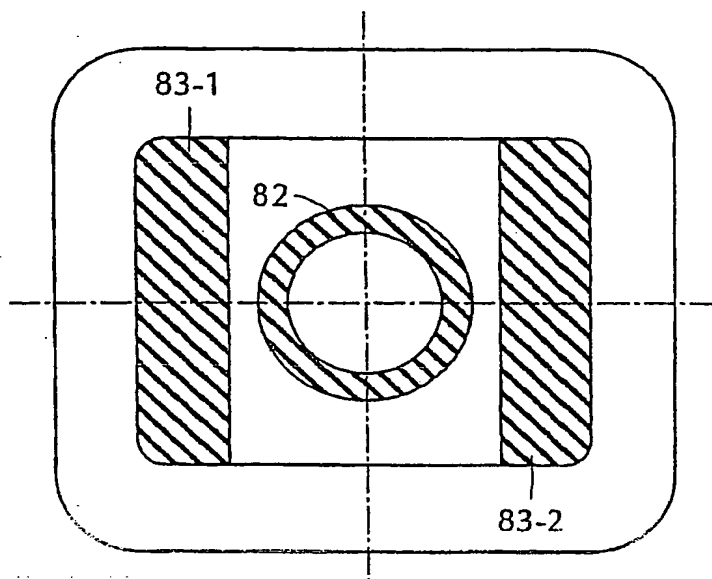
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FIG. 8B

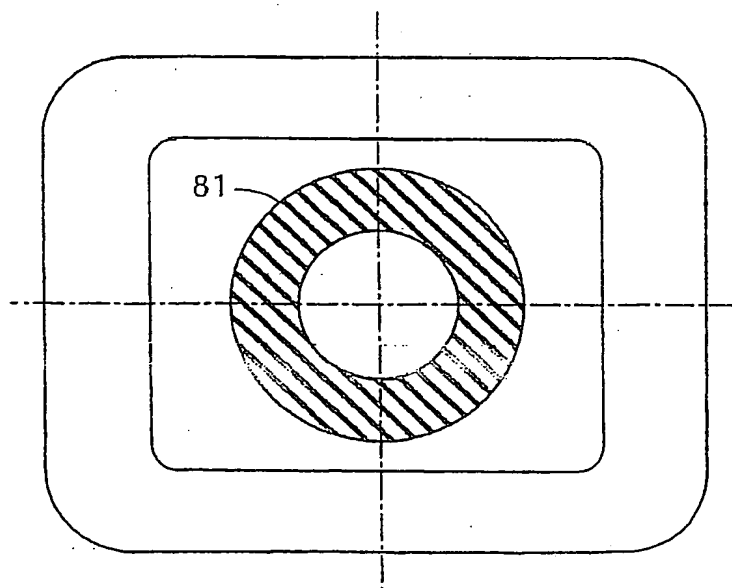


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**FIG. 8C**

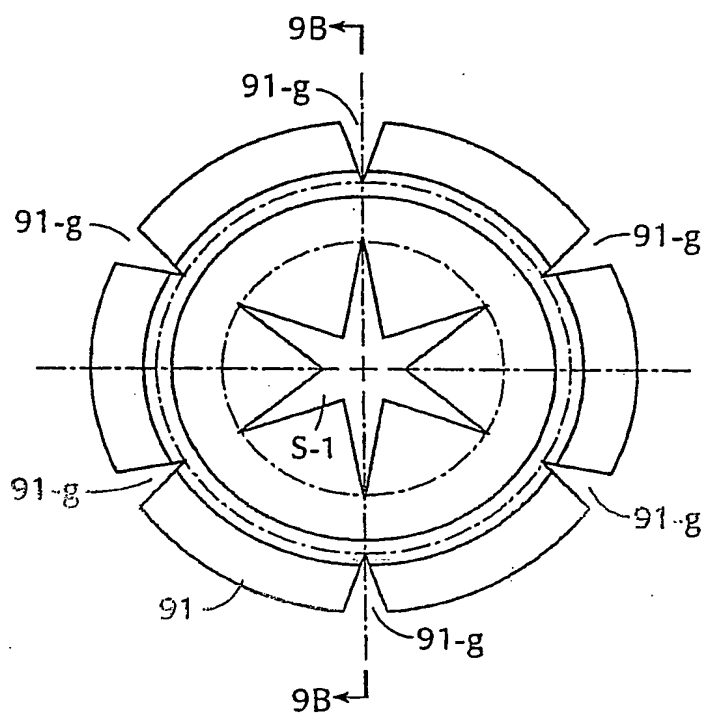


**FIG. 8D**



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**FIG. 9A**



**FIG. 9B**

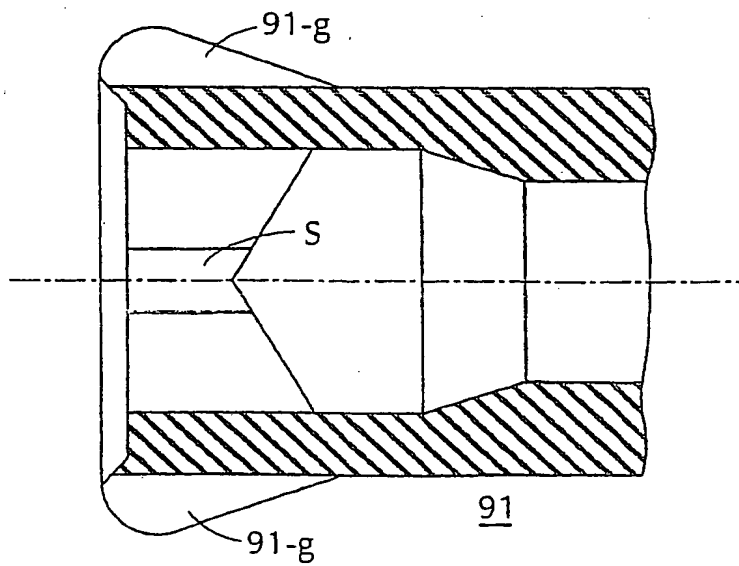


FIG. 10A

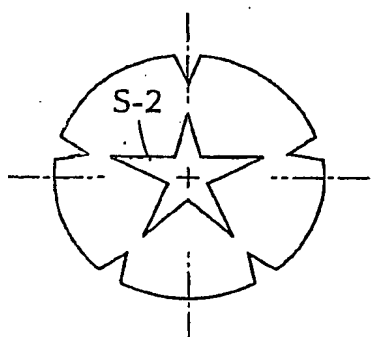


FIG. 10B

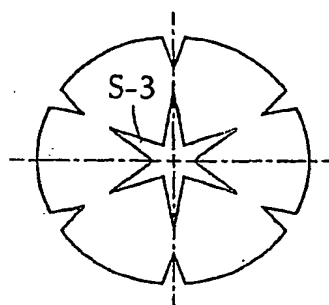


FIG. 10C

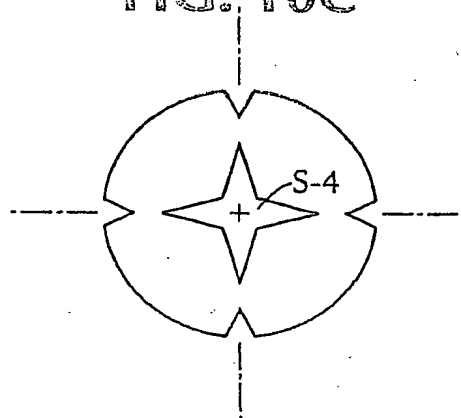


FIG. 10C

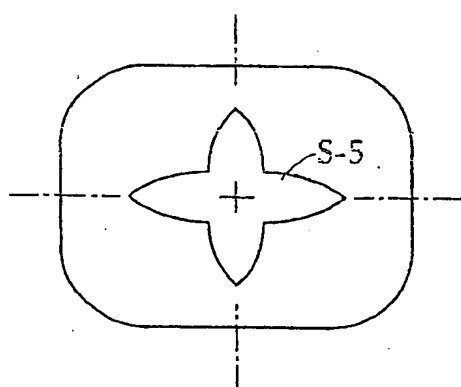
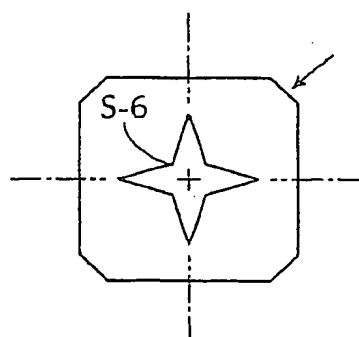


FIG. 10E



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FIG. 11A

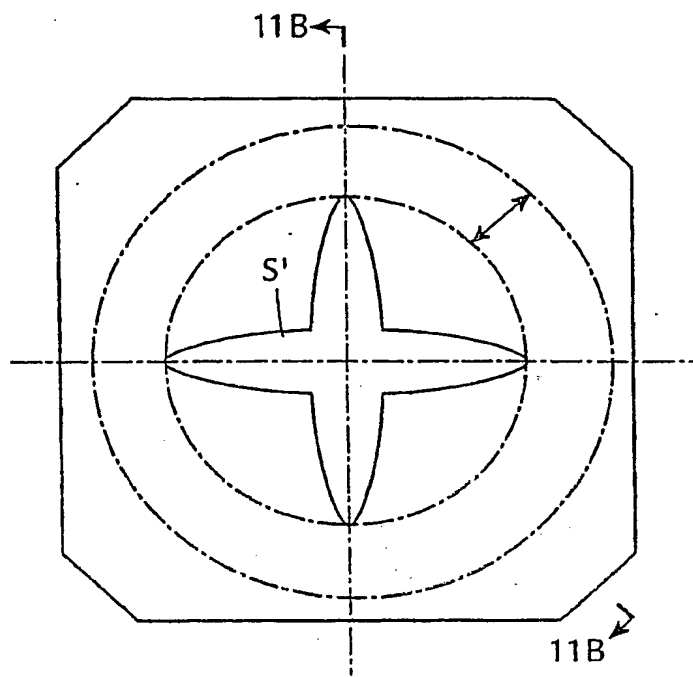
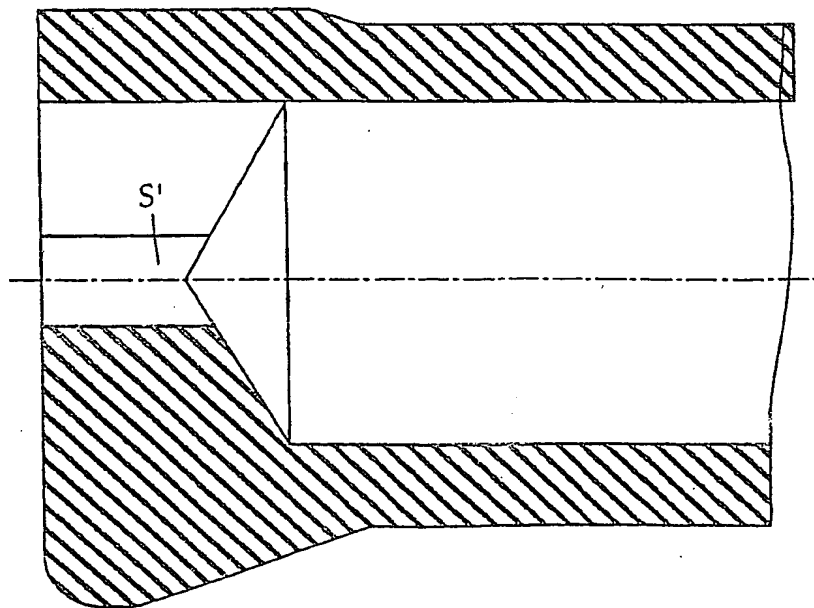


FIG. 11B



## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/03268**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :F16L 37/28

US CL :251/149.1, 149.6; 604/256, 604/905

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 251/149.1, 149.6; 604/256, 604/905

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,085,645 A (PURDY et al) 04 February 1992, see column 5, lines 66+ (molded method disclosed).	1-11, 13-20
X	US 4,710,168 A (SCHWAB et al) 01 December 1987, see column 3, lines 55+.	12



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

07 MAY 1997

Date of mailing of the international search report

24 JUN 1997

Name and mailing address of the ISA/US  
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